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EXAMINER

WANG, SHENGJUN

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1617

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/773,394
Filing Date: January 31, 2001
Appellant(s): WIKLUND ET AL.

Edward A. Meilman
For Appellant

mail date
7-14-04

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 2, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because claims 2, 4-14, 20-21 are all dependent claims of claim 1 with specific amount of the active ingredients or specific administration conditions. The specific amounts or conditions is a matter of optimization and is within the skill of artisan, absent evidence to the

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contrary. Applicants never provide evidence showing the particular amount or conditions would constitute patentable feature.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

US Patent 5,719,119	Veech	February 17, 1998
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US Patent 5,310,768	Vinnars	May 10, 1994
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(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-2, 4-21 are rejected under 35 U.S.C. 103(a)

These rejections are fully set forth in prior office action, paper No. 18.

(11) *Response to Argument*

Claims 1-2, 4-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (USPN 5,719,119) and Vinnars (USPN 5,310,768).

Veech (USPN 5,719,119) teaches a parenteral nutrition solution comprising alpha-ketoglutarate and ammonium, see Table 9, col.20, examples 1.4-1.5. Veech also teaches the employment of the parenteral nutrition solution in a method of normalizing muscle and organ function, see claim 5 for example. Veech further teaches that post-traumatic or post-operative patients suffer from a negative nitrogen balance, col.7, line 55 to column 8 line 7. Veech also

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teaches alpha ketoglutarate and ammonium in an amino acid solution containing glutamate which can control the redox state of the mitochondria and therefore be useful in nitrogen-containing pharmaceutical compositions, see col. 13 line 5 to col. 14 line 20.

Vinnars (USPN 5,310,768) teaches a method of treatment of post operative and Post-traumatic patients for improving glutamine content in skeletal muscle and preventing the reduction of protein synthesis capacity, hence also, improve the nitrogen balance and even make it positive by administering alpha-ketoglutarate, alone or in combination with other actives, see col. 2, lines 54-63 and abstract in particular. Vinnars teaches that the amount of alpha-ketoglutarate is at least 0.1g/kg body weight/day (which amounts to 312.5 micromoles/kg body weight per day), see col. 3, lines 6-12.

Veech and Vinnars do not particularly teach the dosing regimen herein in terms of micromoles per kilogram per minute, nor do they teach the administration of two separate compositions. Neither does it particularly teach the employment of a particular salt of ammonium.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a composition consisting essentially of alpha-ketoglutarate and an ammonium salt in the doses herein in a method of preserving bodily protein in catabolic patients.

One of ordinary skill in the art would have been motivated to employ two separate compositions each consisting essentially of alpha-ketoglutarate or an ammonium salt in the doses herein in a method of preserving bodily protein in catabolic patients because both alpha-ketoglutarate and ammonium are known to be useful in methods of treating post-operative/post-traumatic patients and normalizing/preserving skeletal muscle glutamine/nitrogen content.

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Combining two agents which are known to be useful to improve nitrogen balance and preserve skeletal muscle individually into a single composition useful for the very same purpose is *prima facie* obvious. See *In re Kerkhoven* 205 USPQ 1069. The employment of salts of known actives is within the skill of the Skilled Artisan and is therefore obvious. Optimization of amounts or variations in regimens, i.e., a single composition or two compositions comprising the same actives is within the skill of the artisan and is therefore obvious, absent evidence to the contrary.

Response to Arguments

Appellants conceded that the references on the record teach the *concomitant* administration of alpha-ketoglutarate and ammonium for the same purpose herein claimed, nevertheless argued the claimed subject matter is patentable distinct from the cited prior art since the claims are drawn to two separate compositions, as compared to a single composition disclosed by the prior art. (note *concomitant* herein recited in claim 1 means “existing or occurring concurrently,” see the dictionary definition attached herein). As discussed in the body of the rejection, Veech teaches that the parenteral administration of a composition comprising both ammonium and alpha-ketoglutarate is known to be useful in post-traumatic patients. Optimization of amounts or variations in regimens, i.e., a single composition or two compositions comprising the same actives is within the skill of the artisan and is therefore obvious, absent evidence to the contrary. Note that the ultimate result of both the prior art and the instant claims is indistinguishable. Both methods supply the post-traumatic patient with ammonium and alpha-keto-glutarate *concomitantly*. Note that the variation of regimen is within the purview of the skilled artisan and is therefore obvious.

Appellants aver unexpected benefits residing in the claimed subject matter, yet fail to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). Note that attorney's arguments do not constitute a showing of unexpected results.

Appellants then state that the Vinnar patent does not teach the employment of ammonium in its composition and method.

Note that Vinnar is a secondary reference employed to supplement the teachings of Veech. Moreover, Vinnar teaches that a composition comprising ketoglutarate and no ammonium can be employed in a parenteral nutrition program in post-traumatic patients. Therefore the skilled artisan in possession of the teachings of the prior art references herein can conclude that alpha ketoglutarate alone as well as in combination with ammonium is known to be useful in treating post-traumatic patients since Vinnars teaches a combination with alpha ketoglutarate and Veech teaches a composition comprising both alpha-ketoglutarate and ammonium.

In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Appellants further argue "its seems more logical that one teaching a composition would want all of the components in a single composition so that the least number of composition need be administered. Separating the components in the absence of reasons to do so is illogical." Two


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compositions seems little bit inconvenient compared to a single composition. However, this inconvenience alone would not constitute a distinct patentable feature. Indeed, it is well established that “A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See also *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994)

Appellants’ arguments that claims 2, 4-14 and 20-21 are patentable distinct from claim 1 are not persuasive. As stated in the rejections, “The employment of salts of known actives is within the skill of the Skilled Artisan and is therefore obvious. Optimization of amounts or variations in regimens, i.e., a single composition or two compositions comprising the same actives is within the skill of the artisan and is therefore obvious, absent evidence to the contrary.” Further, the optimization of a result effective parameter, e.g., effective amount of actives, particular regimens, such as those for infusion, is considered within the skill of the artisan. See, *In re Boesch and Slaney* (CCPA) 204 USPQ 215. Appellants provide no evidence that the particular limitation recited in claims 2, 4-14 or 20-21 would lead to any unexpected benefit. Therefore, claims 2, 4-14 and 20-21 should stand or fall together with claim 1. For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

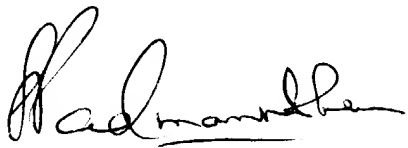

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July 2, 2004

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